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# TRANSMITTAL FORM

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	Application Number	10/788,649
	Filing Date	February 27, 2004
	First Named Inventor	Thomas D. Madden
	Art Unit	1636
	Examiner Name	
	Attorney Docket No.	480208.408D1

## ENCLOSURES (check all that apply)

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Response<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement; Form PTO-1449<br><input checked="" type="checkbox"/> Cited References<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts under 37 C.F.R. 1.52 or 1.53<br><input type="checkbox"/> Response to Missing Parts/Incomplete Application | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Request for Corrected Filing Receipt<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address<br><input type="checkbox"/> Declaration<br><input type="checkbox"/> Statement under 37 CFR 3.73(b)<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund | <input type="checkbox"/> CD(s), Number of CD(s) _____<br><input type="checkbox"/> After Allowance Communication to Technology Center (TC)<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Return Receipt Postcard<br><input type="checkbox"/> Additional Enclosure(s) (please identify below):<br><hr/> <hr/> <hr/> <hr/> |
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## Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Individual Name	Carol D. Laherty, Ph.D.	Customer Number
Signature		
Date	September 15, 2004	

## CERTIFICATE OF TRANSMISSION/MAILING

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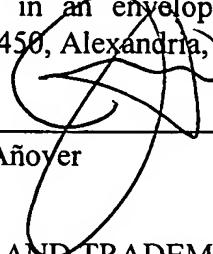
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PATENT

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September 15, 2004  
Date

  
Jason Añoyer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Thomas D. Madden et al.  
Application No. : 10/788,649  
Filed : February 27, 2004  
For : LIPOSOMAL ANTINEOPLASTIC DRUGS AND USES THEREOF

Art Unit : 1636  
Docket No. : 480208.408D1  
Date : September 15, 2004

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 CFR 1.56 and 1.97 through 1.98, applicants wish to make known to the U.S. Patent and Trademark Office the references set forth on the attached Form PTO-1449. Applicants note that since the application filing date is after June 30, 2003, copies of the cited U.S. patents and published patent applications are not required and accordingly have not been provided. Copies of all other cited references are enclosed. As to any reference cited, applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any such reference, as by a showing under 37 CFR 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with applicants' duty to disclose all information they are aware of which is

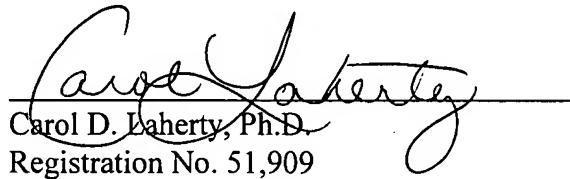
believed relevant to the examination of the above-identified application, applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Information Disclosure Statement has been timely filed, however, the Director is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,

Seed Intellectual Property Law Group PLLC



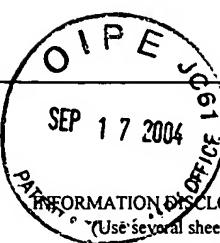
Carol D. Laherty, Ph.D.  
Registration No. 51,909

Enclosures:

Postcard  
Form PTO-1449  
Cited References (28)

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FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 480208.408D1	APPLICATION NO. 10/788,649
  SEP 17 2004				APPLICANTS Thomas D. Madden et al.	
				FILING DATE February 27, 2004	GROUP ART UNIT 1636

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	4,235,871	11/25/80	Papahadjopoulos et al.	424	19	
AB	4,501,728	02/26/85	Geho et al.	424	38	
AC	4,837,028	06/06/89	Allen	424	450	
AD	5,023,087	06/11/91	Yau-Young	424	450	
AE	5,552,156	09/03/96	Burke	424	450	
AF	5,814,335	09/29/98	Webb et al.	424	450	
AG	5,837,282	11/17/98	Fenske et al.	424	450	
AH	5,976,567	11/02/99	Wheeler et al.	424	450	
AI	6,110,491	08/29/00	Kirpotin	424	450	
AJ	6,355,268	03/12/02	Slater et al.	424	450	

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES      NO
	AK	WO 95/08986	04/06/95	WIPO	
	AL	WO 98/17256	04/30/98	WIPO	
	AM	WO 99/51202	10/14/99	WIPO	
	AN	WO 00/23052	04/27/00	WIPO	
	AO	WO 99/13816	03/25/99	WIPO	

**OTHER PRIOR ART** (*Including Author, Title, Date, Pertinent Pages, Etc.*)

AP		Burris, H., et al., "Activity of Topotecan, a New Topoisomerase I Inhibitor, Against Human Tumor Colony-Forming Units In Vitro," <i>J. Natl. Cancer Inst.</i> 84(23):1816-1820, December 2, 1992.
AQ		Clements, M., et al., "Antiangiogenic Potential of Camptothecin and Topotecan," <i>Cancer Chemother. Pharmacol.</i> 44:Pages 411-416, 1999.

EXAMINER	DATE CONSIDERED

\* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 480208.408D1	APPLICATION NO. 10/788,649
INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		APPLICANTS Thomas D. Madden et al.			
		FILING DATE February 27, 2004	GROUP ART UNIT 1636		

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	BA	60/215,556		Madden et al.			06/30/00
	BB	09/896,812		Madden et al.			06/29/01
	BC	60/264,616		Madden et al.			01/26/01

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	BD					

**OTHER PRIOR ART** (*Including Author, Title, Date, Pertinent Pages, Etc.*)

BE		Corbett, T., et al., chapter 5 "In Vivo Methods for Screening and Preclinical Testing," in B. Teicher, Ed., <i>Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997, pp.75-99.
BF		Emerson, D., et al., "In Vivo Antitumor Activity of Two New Seven-substituted Water-soluble Camptothecin Analogues," <i>Cancer Res.</i> 55:603-609, February 1, 1995.
BG		Erickson-Miller, C., et al., "Differential Toxicity of Camptothecin, Topotecan and 9-Aminocamptothecin to Human, Canine, and Murine Myeloid Progenitors (CFU-GM) in Vitro," <i>Cancer Chemother. Pharmacol.</i> 39:467-472, 1997.
BH		Grochow, L., et al., "Pharmacokinetics and Pharmacodynamics of Topotecan in Patients with Advanced Cancer," <i>Drug Metab. Dispos.</i> 20(5):706-713, 1992.
BI		Hardman, W., et al., "Efficacy of Treatment of Colon, Lung and Breast Human Carcinoma Xenografts With: Doxorubicin, Cisplatin, Irinotecan or Topotecan," <i>Anticancer Res.</i> 19:2269-2274, 1999.
BJ		Hope, M., et al., "Generation of Multilamellar and Unilamellar Phospholipid Vesicles," <i>Chem. Phys. Lip.</i> 40:89-107, 1986.
BK		Hsiang, Y-H., et al., "Identification of Mammalian DNA Topoisomerase I as an Intracellular Target of the Anticancer Drug Camptothecin," <i>Cancer Res.</i> 48:1722-1726, April 1988.
BL		Kearney, A. et al., "Preformulation Studies to Aid in the Development of a Ready-to-Use Injectable Solution of the Antitumor Agent, Topotecan," <i>Int. J. Pharm.</i> 127:229-237, 1996.
BM		Gruner, S., chapter 1 "Materials Properties of Liposomal Bilayers," in Ostro, M.J. (ed.), <i>Liposomes: From Biophysics to Therapeutics</i> , Marcel Dekker, New York, 1993, pp. 1-38.
BN		Madden, T., et al. "The Accumulation of Drugs Within Large Unilamellar Vesicles Exhibiting a Proton Gradient: A Survey," <i>Chem. Phys. Lipids</i> 53:37-46, 1990.

EXAMINER	DATE CONSIDERED
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INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			APPLICANTS Thomas D. Madden et al.			
			FILING DATE February 27, 2004	GROUP ART UNIT 1636		

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA						

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
				YES	NO
	CB				

**OTHER PRIOR ART** (*Including Author, Title, Date, Pertinent Pages, Etc.*)

CC	Madden, T., et al., "Encapsulation of Topotecan in Lipid-based Carrier Systems. Evaluation of Drug Stability and Plasma Elimination in a Murine Model, and Comparison of Antitumor Efficacy Against Murine L1210 and B16 Tumors," <i>Proc. Of ASCO 17</i> , abstract #754, 1998.
CD	Mayer, L., et al., "Characterization of Liposomal Systems Containing Doxorubicin Entrapped in Response to pH Gradients," <i>Biochim. Biophys. Acta</i> 1025:143-151, 1990.
CE	McCabe, F., et al., "Comparative Activity of Oral and Parenteral Topotecan in Murine Tumor Models: Efficacy of Oral Topotecan," <i>Cancer Invest.</i> 12(3):308-313, 1994.
CF	O'Leary, J., et al., "Antiangiogenic Effects of Camptothecin Analogues 9-Amino-20 (S)-Camptothecin, Topotecan, and CPT-11 Studied in the Mouse Cornea Model," <i>Clin Cancer Res.</i> 5:181-187, January 1999.
CG	Ormrod, D. et al., "Topotecan A Review of its Efficacy in Small Cell Lung Cancer," <i>Drugs</i> 58(3):533-551, September 1999.
CH	Plowman, J., et al., chapter 6, "Human Tumor Xenograft Models in NCI Drug Development," in B. Teicher, Ed, <i>In Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997.
CI	Szoka, F., et al., "Comparative Properties and Methods of Preparation of Lipid Vesicles (Liposomes)," <i>Ann. Rev. Biophys. Bioeng.</i> 9:467- 508, 1980.
CJ	Tardi, P., et al., "Liposomal Encapsulation of Topotecan Enhances Anticancer Efficacy in Murine and Human Xenograft Models," <i>Cancer Res.</i> 60:3389-3393, July 2000.
CK	Thompson, J., et al., "Animal Models for Studying the Action of Topoisomerase I Targeted Drugs," <i>Biochim. Biophys. Acta</i> 1400:301-319, 1998.
CL	Wall, M., et al., "Plant Antitumor Agents. I. The Isolation and Structure of Camptothecin, a Novel Alkaloidal Leukemia and Tumor Inhibitor from Camptotheca Acuminata," <i>J. Am Chem. Soc.</i> 88:3888-3890, August 1966.
CM	Waud, W., chapter 4 "Murine L1210 and P388 Leukemias," In B. Teicher, Ed, <i>Anticancer Drug Development Guide: Preclinical Screening, Clinical Trials, and Approval</i> , Humana Press Inc., Totowa, NJ, 1997.

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